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EXAMINER

NAFF, DAVID M

ART UNIT PAPER NUMBER

1651

DATE MAILED: 01/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/785,188

Applicant(s)

CONROY ET AL.

Examiner

David M. Naff

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 and 31-36 is/are pending in the application.
- 4a) Of the above claim(s) 1-14 and 27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15-26, 28, 29 and 31-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

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A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/22/03 has been entered.

The submission presented arguments and did not amend the claims. Therefore, the claims in the case are those listed in a response of 7/28/03.

Claims pending in the application are 1-29 and 31-36. The remarks filed 10/22/03 at page 5, bridging lines 1 and 2, incorrectly state that the pending claims are 1-29 and 31-37. There is no claim 37.

Claims 1-14 and 27 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 10 filed 7/26/02.

Claims examined on the merits are 15-26, 28, 29 and 31-36.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 103

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Claims 26, 28, 29 and 31-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Uo et al (AL) in view of Hino et al (4,148,689).

Claim 26 is drawn to mixing a vegetative cell into a sol, mixing
5 a dispersant into the sol to cause macropores in a gel formed by the sol and gelling the sol. Claim 28 requires gel containing a macroporous solid network formed by condensing hydroxy metallates from a sol solution containing a bacterial cell. Claims 29 and 31-36 are drawn to the same type of gel as claim 28 except that the cell is a
10 vegetative cell.

Uo et al disclose immobilization of yeast cells in a porous silica carrier with the sol-gel process by forming a mixture containing tetramethoxysilane (TMOS), water, and PEG, hydrolyzing to form a sol, adding yeast spores, and forming a gel. See paragraph 2.3
15 on page 427. The porous gel can have pore diameters ranging from 0.1 m to 10 m which are macropores (page 429, paragraph 4).

Hino et al disclose hydrolyzing an alkoxysilane to form a sol, adding such as bacterial cells or yeast cells (col 7, lines 1-47) and gelling the sol to obtain a gel with the cells immobilized therein.

20 It would have been obvious to use bacterial cells in place of the yeast spores of Uo et al when the function of bacterial cells is desired as suggested by Hino et al producing a gel by a method similar to that of Uo et al and using bacterial cells. To use the bacterial cells in the vegetative state would have been obvious since this is

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the state the cells normally are present. The resultant gel would have inherently transmitted light as required by claims 31-35.

Response to Arguments

Applicants argue that the claims are directed to a solid network
5 defining macropores or to gelling a sol to form a gel that has
macropores. This argument is unpersuasive since both Uo et al and
Hino et al produce a network or gel having macropores by gelling a
sol. The gel produced by Hino et al contains macropores due to
addition of a polymer such as polyethylene glycol (col 4, line 62)
10 functioning as a dispersant to form macropores as described in the
present specification (paragraph bridging pages 4 and 5, page 8, lines
10-11, and page 9, lines 13-19). The cells of Hino et al are entrapped
in the gel (col 6, lines 55-60). When used to act on a substrate such
as in a column as disclosed by Hino et al (col 9, lines 59-68), the
15 substrate must pass into the gel. Effective conversion of a substrate
continuously passing through a column containing the gel will require
the gel contain macropores so the substrate can enter the gel and be
converted by the cells. The gel produced by Uo et al also contains
macropores since polyethylene glycol is added to the sol.

20 In regard to Uo et al requiring an organic solvent that may be
toxic to vegetative cells, the present claims do not exclude an organic
solvent, and do not exclude the harmful affect of an organic solvent on
the cells. The present specification discloses having an organic
solvent in the sol (paragraph bridging pages 4 and 5), and the claims
25 require nothing to avoid the toxicity of the organic solvent. If one

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ignores toxicity of the solvent on vegetative cells, the use of vegetative cells in combination with the solvent is obvious.

Furthermore, Hino et al suggest that the organic solvent can be omitted by forming a sol and gel therefrom substantially as Uo et al without
5 using an organic solvent. Knowing that an organic solvent is toxic to vegetative cells as disclosed by Uo et al, one will obviously omit the solvent as in Hino et al when vegetative cells are used.

Applicants urge that the claims need not exclude an organic solvent. However, if not excluded, the claims encompass the use of an
10 organic solvent. The present specification discloses the use of an organic solvent, and discloses no way of avoiding its harmful toxicity. In any event, it is clear from Hino et al that the organic solvent can be omitted.

In regard to claim 28, applicants urge that neither Uo et al or
15 Hino et al describe or suggest a bacterial spore immobilized in a macroporous solid network. However, it would have been obvious to use a bacterial spore in Uo et al when the function of a bacterial cell is desired as disclosed by Hino et al since the sol and gel forming methods of Uo et al and Hino et al are very similar. Since Uo et al
20 disclose that an organic solvent used is toxic to yeast cells not in spore form, it would have been obvious to use a bacterial spore when bacteria rather than yeast is being entrapped in the gel. In addition, claim 28 does not exclude an organic solvent that applicants urge is required by Uo et al and is toxic to cells not in spore form.

Claims 15-23 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claims 26, 28, 29 and 31-36 above, and further in view of Klein et al (EJ) and Rao et al (AR).

5 The claims require a sol containing a P moles of hydroxy metallate, W moles of water, dispersant to cause macropores in a gel formed from the sol and a biological material, and a ratio of W:P greater than 25:1.

10 Klein et al disclose the effect of water on hydrolysis of TEOS and Rao et al disclose the influence ratios of precursor, catalyst, solvent and water on properties of silica aerogels.

15 It would have been a matter of obvious choice and require only limited routine experimentation to select a preferred optimum amount of water in Uo et al in view of the disclosures of Klein et al and Rao et al as to the effect of varying the water content.

Response to Arguments

20 In regard to claim 15, applicants urge that there is no requirement, statutory or otherwise, that the claim contains a teaching away from a combination of references. However, there is a statutory requirement that the claimed invention be unobvious. When the claimed invention encompasses elements the references teach, the invention cannot be unobvious for not using the elements. Claim 15 encompasses yeast spores and an organic solvent as disclosed by Uo et al, and the present specification discloses that an organic solvent can be present.

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Applicants urge that arguing that claim 15 does not exclude spores, and that an organic solvent can be used in combination with spores as disclosed by Uo et al represents an unjustified shifting of the burden of proof to applicants to establish with certainty that the proposed combination will not succeed, rather than requiring the office to establish a suggestion to combine the cited references and a reasonable expectation of success with the combination. However, the disclosures of the references clearly provide a suggestion and motivation for combining their teachings as stated in the rejection to establish a *prima facie* case of obviousness. When *prima facie* obviousness is established, the burden of proof properly shifts to applicants. Furthermore, if applicants establish that a combination will not succeed, the claims must be limited to not encompass the combination, and be unobvious from the combination.

Applicants urge that Klein et al require excess ethanol to permit solubility of the additional water. However, the present specification discloses that an organic solvent can be present, and claim 15 encompasses the amount of ethanol used by Klein et al. It would have been obvious to use in Uo et al the higher amount of water disclosed by Klein et al to obtain the results of a higher amount of water taught by Klein et al.

Applicants urge that it is unclear why the properties disclosed by Klein et al resulting from the water content used would be desirable in the claimed invention. However, an increased rate of hydrolysis from a higher amount of water taught by Klein et al would have obviously been

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advantageous to produce the sol of Uo et al and of claim 15 to shorten the time required for hydrolysis. The biological material of claim 15 can be a spore, and Uo et al disclose that using a spore avoids the toxicity of an organic solvent that can be present in claim 15 as
5 described in the specification. When the references are considered together as a whole, the invention of claim 15 and claims dependent thereon is clearly *prima facie* obvious.

Claim Rejections - 35 USC § 103

Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable
10 over the references as applied to claims 15-23 and 25 above, and further in view of Schmidt et al (AV).

The claim requires an organic solvent to be produced as a by-product of hydrolysis.

Schmidt et al disclose that hydrolysis of alkoxysilanes produces
15 an alcohol.

It would have been obvious that hydrolysis in Uo et al will produce an alcohol as taught by Schmidt et al.

Response to Arguments

No arguments were presented traversing the rejection over Schmidt
20 et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff whose telephone number is 703-308-0520. The examiner can normally be reached on Monday-Friday 9:30-6:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 703-308-4743. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

5 Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

10



David M. Naff
Primary Examiner
Art Unit 1651

DMN

15 1/9/04